IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD., and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC.,	)	**JURY TRIAL DEMANDED**
Plaintiffs,	)	
v.	)	C.A. No. 16-cv-00952 (SLR)
SANDOZ INC.,	)	
Defendant.	)	

SANDOZ INC.'S ANSWER, DEFENSES AND AMENDED COUNTERCLAIMS

Defendant Sandoz Inc. ("Sandoz"), for its Answer, Defenses and Amended Counterclaims to the Complaint for Patent Infringement of Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, "Plaintiffs") (D.I. 1), responds as follows. Every allegation not expressly admitted herein is denied.

THE PARTIES

1. Paragraph 1 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz lacks knowledge or information sufficient to form a belief as to the truth of any and all remaining allegations of Paragraph 1, and therefore denies any and all remaining allegations of Paragraph 1.

2. Paragraph 2 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz lacks knowledge or information sufficient to form a belief as to the truth of any and all allegations of Paragraph 2, and therefore denies any and all allegations of Paragraph 2.

3. Paragraph 3 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz lacks knowledge or information sufficient to form a belief as to the truth of any and all remaining allegations of Paragraph 3, and therefore denies any and all remaining allegations of Paragraph 3.

4. Sandoz admits that it is a corporation organized and existing under the laws of the State of Colorado with a place of business at 100 College Road West, Princeton, NJ 08540. Further answering, Sandoz admits that it develops, manufactures, and sells pharmaceutical products in the United States, including quality generic medicines. Sandoz denies any and all remaining allegations of Paragraph 4.

5. Paragraph 5 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that it submitted Abbreviated New Drug Application ("ANDA") No. 209441 to the United States Food and Drug Administration ("FDA") seeking approval for mirabegron extended-release tablets, 25 mg and 50 mg. Sandoz denies any and all remaining allegations of Paragraph 5.

NATURE OF ACTION

6. Paragraph 6 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that Plaintiffs' Complaint purports to state a claim for alleged infringement of United States Patent Nos. 7,342,117 ("the '117 patent"), 7,982,049 ("the '049 patent"), 8,835,474 ("the '474 patent"), and RE44,872 ("the '872 patent"). Further answering, Sandoz admits that it submitted ANDA No. 209441 to FDA seeking approval for mirabegron extended-release tablets, 25 mg and 50 mg. Sandoz denies any and all remaining allegations of Paragraph 6.

JURISDICTION AND VENUE

7. Paragraph 7 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that subject matter jurisdiction is proper, if at all, solely for Plaintiffs' alleged infringement claims against Sandoz under 35 U.S.C. § 271(e)(2)(A). Sandoz denies that subject matter jurisdiction is proper for any claims asserted against Sandoz under 35 U.S.C. § 271(a), (b) or (c). Sandoz denies any and all remaining allegations of Paragraph 7.

8. Paragraph 8 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, denied. Further answering, Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only.

9. Paragraph 9 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that it develops, manufactures, and sells pharmaceutical products in the United States, including quality generic medicines. Sandoz denies any and all remaining allegations of Paragraph 9.

10. Paragraph 10 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that it submitted an ANDA to the FDA seeking approval for mirabegron extended-release tablets, 25 mg and 50 mg, prior to the expiration of the '117, '049, '474 and '872 patents. Sandoz denies any and all remaining allegations of Paragraph 10.

11. Paragraph 11 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that it sent a letter, dated September 9, 2016, titled "Notice of Certification Under 21 U.S.C. § 355(j)(2)(B) (§505(j)(2)(B)) of Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95 Sandoz Inc.'s Mirabegron Extended-

Release Tablets, 25 mg and 50 mg Sandoz Inc.'s ANDA No. 209441" ("Sandoz Inc.'s Notice Letter") to Astellas Americas, Astellas Pharma Global Development, Inc. and Astellas Pharma Inc. Sandoz denies any and all remaining allegations of Paragraph 11.

12. Denied.

13. Paragraph 13 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, denied. Further answering, Sandoz does not contest venue in this judicial district solely for the limited purpose of this action only.

FACTUAL BACKGROUND

A. The '117 Patent

14. Paragraph 14 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that, according to the online records of the United States Patent and Trademark Office ("PTO"), the '117 patent, which is titled "α-Form or β-Form Crystal of Acetanilide Derivative," issued on or about March 11, 2008. Sandoz further admits that what purports to be a copy of the '117 patent is attached to Plaintiffs' Complaint as Exhibit A. Sandoz denies that the '117 patent was duly and legally issued, as well as any suggestion that the '117 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 14.

15. Paragraph 15 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that the '117 patent is titled "α-Form or β-Form Crystal of Acetanilide Derivative." Sandoz denies any and all remaining allegations of Paragraph 15.

16. Paragraph 16 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that the electronic version of FDA's

Orange Book lists the '117 patent in connection with MYRBETRIQ®, with a purported expiration date of November 4, 2023. Sandoz denies any and all remaining allegations of Paragraph 16.

B. The '049 Patent

17. Paragraph 17 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that, according to the online records of the PTO, the '049 patent, which is titled "α-Form or β-Form Crystal of Acetanilide Derivative," issued on or about July 19, 2011. Sandoz further admits that what purports to be a copy of the '049 patent is attached to Plaintiffs' Complaint as Exhibit B. Sandoz denies that the '049 patent was duly and legally issued, as well as any suggestion that the '049 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 17.

18. Paragraph 18 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that the '049 patent is titled "α-Form or β-Form Crystal of Acetanilide Derivative." Sandoz denies any and all remaining allegations of Paragraph 18.

19. Paragraph 19 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that the electronic version of FDA's Orange Book lists the '049 patent in connection with MYRBETRIQ®, with a purported expiration date of November 4, 2023. Sandoz denies any and all remaining allegations of Paragraph 19.

C. The '474 Patent

20. Paragraph 20 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that, according to the online records of the PTO, the '474 patent, which is titled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient," issued on or about September 16, 2014. Sandoz further admits that what purports to be a copy of the '474 patent is attached to Plaintiffs'

Complaint as Exhibit C. Sandoz denies that the '474 patent was duly and legally issued, as well as any suggestion that the '474 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 20.

21. Paragraph 21 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that the '474 patent is titled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient." Sandoz denies any and all remaining allegations of Paragraph 21.

22. Paragraph 22 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that the electronic version of FDA's Orange Book lists the '474 patent in connection with MYRBETRIQ®, with a purported expiration date of November 4, 2023. Sandoz denies any and all remaining allegations of Paragraph 22.

D. The '872 Patent

23. Paragraph 23 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that, according to the online records of the PTO, the '872 patent, which is titled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient," issued on or about April 29, 2014. Sandoz further admits that what purports to be a copy of the '872 patent is attached to Plaintiffs' Complaint as Exhibit D. Sandoz denies that the '872 patent was duly and legally issued, as well as any suggestion that the '872 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 23.

24. Paragraph 24 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that the '872 patent is titled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient." Sandoz denies any and all remaining allegations of Paragraph 24.

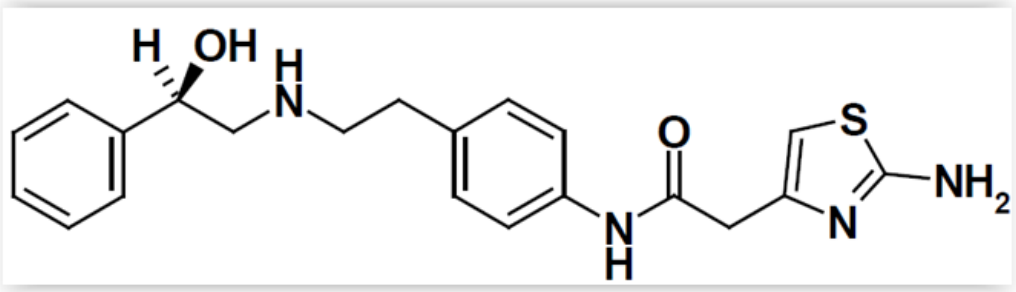
25. Paragraph 25 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that the '872 patent is titled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient." Sandoz denies any and all remaining allegations of Paragraph 25.

26. Paragraph 26 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that the electronic version of FDA's Orange Book lists the '872 patent in connection with MYRBETRIQ®, with a purported expiration date of November 4, 2023. Sandoz denies any and all remaining allegations of Paragraph 26.

E. Myrbetriq®

27. Paragraph 27 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that the electronic version of FDA's Orange Book identifies "MYRBETRIQ" for New Drug Application ("NDA") No. 202611 for "MIRABEGRON", "TABLET, EXTENDED RELEASE; ORAL." Sandoz further admits that the electronic version of FDA's Orange Book lists, *inter alia*, the '532, '117, '049, '474 and '872 patents in connection with MYRBETRIQ®. Sandoz denies any and all remaining allegations of Paragraph 27.

28. Paragraph 28 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that the current FDA-approved label and prescribing information for MYRBETRIQ® states that "[t]he chemical name is 2-(2-aminothiazol-4-yl)-N-[4-(2-{[(2R)-2-hydroxy2-phenylethyl]amino}ethyl)phenyl]acetamide." Sandoz further admits that the current FDA-approved label and prescribing information for MYRBETRIQ® states that "[t]he structural formulation of mirabegron is:



."

Sandoz denies any and all remaining allegations of Paragraph 28.

29. Paragraph 29 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that the current FDA-approved label and prescribing information for MYRBETRIQ® states that "MYRBETRIQ® is a beta-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency." Sandoz denies any and all remaining allegations of Paragraph 29.

30. Paragraph 30 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that each of the '532, '117, '049, '474 and '872 patents identify "Astellas Pharma Inc." as the purported "Assignee." Sandoz lacks knowledge or information sufficient to form a belief as to the truth of any and all remaining allegations of Paragraph 30, and therefore denies any and all remaining allegations of Paragraph 30.

31. Paragraph 31 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz lacks knowledge or information sufficient to form a belief as to the truth of any and all allegations of Paragraph 31, and therefore denies any and all allegations of Paragraph 31.

32. Paragraph 32 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz lacks knowledge or information sufficient to

form a belief as to the truth of any and all allegations of Paragraph 32, and therefore denies any and all allegations of Paragraph 32.

F. Sandoz

33. Paragraph 33 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that it submitted ANDA No. 209441 to FDA seeking approval for mirabegron extended-release tablets, 25 mg and 50 mg, prior to the expiration of the ’117, ’049, ’474 and ’872 patents. Sandoz denies any and all remaining allegations of Paragraph 33.

34. Paragraph 34 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that it submitted an ANDA to FDA seeking approval of mirabegron extended-release tablets, 25 mg and 50 mg, prior to the expiration of the ’117, ’049, ’474 and ’872 patents. Sandoz denies any and all remaining allegations of Paragraph 34.

35. Paragraph 35 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that Sandoz Inc.’s Notice Letter provided written notification of Sandoz’s ANDA for mirabegron extended-release tablets, 25 mg and 50 mg, and so-called “paragraph IV certifications” to the ‘117, ‘049, ‘474 and ‘872 patents, stating that, in Sandoz’s opinion and to the best of its knowledge, such patents are invalid, unenforceable, and/or not infringed. Sandoz further admits that Sandoz Inc.’s Notice Letter satisfies all statutory and regulatory requirements. Sandoz denies any and all remaining allegations of Paragraph 35.

36. Paragraph 36 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that the face of ‘532 patent, which is titled “Amide Derivatives Or Salts Thereof,” identifies “Yamanouchi Pharmaceutical Co., Ltd.” as the

purported "assignee." Sandoz further admits that it submitted an ANDA to FDA seeking approval of mirabegron extended-release tablets, 25 mg and 50 mg, prior to expiration of the '117, '049, '474 and '872 patents. Sandoz denies any and all remaining allegations of Paragraph 36.

37. Denied.

38. Paragraph 38 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that the electronic court records of the United States District Court for the District of Delaware indicate that a Complaint was docketed against Sandoz Inc. on or about October 14, 2016. Sandoz denies any and all remaining allegations of Paragraph 38.

COUNT I: THE '117 PATENT

39. Sandoz restates and incorporates by reference each of its responses to Paragraphs 1 through 38, as if fully set forth herein.

40. Denied.

41. Denied.

42. Denied.

COUNT II: THE '049 PATENT

43. Sandoz restates and incorporates by reference each of its responses to Paragraphs 1 through 42, as if fully set forth herein.

44. Denied.

45. Denied.

46. Denied.

COUNT III: THE '474 PATENT

47. Sandoz restates and incorporates by reference each of its responses to

Paragraphs 1 through 46, as if fully set forth herein.

48. Denied.

49. Denied.

COUNT IV: THE '474 PATENT

50. Sandoz restates and incorporates by reference each of its responses to Paragraphs 1 through 49, as if fully set forth herein.

51. Paragraph 51 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that it submitted an ANDA to the FDA seeking approval for mirabegron extended-release tablets, 25 mg and 50 mg, and that its ANDA contains a paragraph IV certification to the '474 patent. Sandoz denies any and all remaining allegations of Paragraph 51.

52. Denied.

53. Denied.

54. Denied.

55. Denied.

56. Denied.

57. Denied.

58. Denied.

COUNT V: THE '474 PATENT

59. Sandoz restates and incorporates by reference each of its responses to Paragraphs 1 through 58, as if fully set forth herein.

60. Paragraph 60 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that it submitted ANDA No. 209441 to

FDA seeking approval of mirabegron extended-release tablets, 25 mg and 50 mg. Sandoz denies any and all remaining allegations of Paragraph 60.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

COUNT VI: THE '872 PATENT

65. Sandoz restates and incorporates by reference each of its responses to Paragraphs 1 through 64, as if fully set forth herein.

66. Denied.

67. Denied.

COUNT VII: THE '872 PATENT

68. Sandoz restates and incorporates by reference each of its responses to Paragraphs 1 through 67, as if fully set forth herein.

69. Paragraph 69 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that it submitted an ANDA to FDA seeking approval for mirabegron extended-release tablets, 25 mg and 50 mg, and that its ANDA contains a paragraph IV certification to the '872 patent. Sandoz denies any and all remaining allegations of Paragraph 69.

70. Denied.

71. Denied.

72. Denied.

73. Denied.

74. Denied.

75. Denied.

76. Denied.

COUNT VIII: THE '872 PATENT

77. Sandoz restates and incorporates by reference each of its responses to Paragraphs 1 through 76, as if fully set forth herein.

78. Paragraph 78 contains legal conclusions for which no answer is required. To the extent that Sandoz is required to answer, Sandoz admits that it submitted ANDA No. 209441 to FDA seeking approval of mirabegron extended-release tablets, 25 mg and 50 mg. Sandoz denies any and all remaining allegations of Paragraph 78.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

PRAYER FOR RELIEF

Sandoz Inc. denies all allegations not expressly admitted herein. Sandoz Inc. further denies that Plaintiffs are entitled to any of the relief requested or to any relief whatsoever. Sandoz Inc. respectfully requests that the Court: (a) dismiss this action with prejudice; (b) enter judgment in favor of Sandoz Inc.; (c) award Sandoz Inc. its reasonable attorney fees and costs incurred in defending this action pursuant to, *inter alia*, 35 U.S.C. § 285; and (d) award Sandoz Inc. such further relief as the Court deems just and appropriate.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting any allegation in the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Sandoz Inc. asserts the following separate defenses:

First Defense

The Complaint fails to state a claim upon which relief can be granted.

Second Defense

The claims of the '117 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for double-patenting.

Third Defense

The claims of the '049 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for double-patenting.

Fourth Defense

The claims of the '474 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for double-patenting.

Fifth Defense

The claims of the '872 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for double-patenting.

Sixth Defense

The manufacture, use, sale, offer for sale, importation, and/or marketing of the mirabegron extended-release tablets, 25 mg and 50 mg, products that are the subject of Sandoz Inc.'s ANDA

have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '117 patent, either literally or under the doctrine of equivalents.

Seventh Defense

The manufacture, use, sale, offer for sale, importation, and/or marketing of the mirabegron extended-release tablets, 25 mg and 50 mg, products that are the subject of Sandoz Inc.'s ANDA have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '049 patent, either literally or under the doctrine of equivalents.

Eighth Defense

The manufacture, use, sale, offer for sale, importation, and/or marketing of the mirabegron extended-release tablets, 25 mg and 50 mg, products that are the subject of Sandoz Inc.'s ANDA have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '474 patent, either literally or under the doctrine of equivalents.

Ninth Defense

The manufacture, use, sale, offer for sale, importation, and/or marketing of the mirabegron extended-release tablets, 25 mg and 50 mg, products that are the subject of Sandoz Inc.'s ANDA have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '872 patent, either literally or under the doctrine of equivalents.

Tenth Defense

Sandoz Inc. has not induced, does not induce, and will not induce infringement of any valid

and/or enforceable claim of the ‘474 patent.

Eleventh Defense

Sandoz Inc. has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the ‘872 patent.

Twelfth Defense

Sandoz Inc. has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the ‘474 patent.

Thirteenth Defense

Sandoz Inc. has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the ‘872 patent.

Fourteenth Defense

The Court lacks subject lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and (c).

Fifteenth Defense

The Complaint fails to state a claim for willful infringement and/or exceptional case.

Sixteenth Defense

Any additional defenses or counterclaims that discovery may reveal, including unenforceability.

* * *

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Sandoz Inc., for its Amended Counterclaims against Plaintiffs/Counterclaim-Defendants Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively "Counterclaim-Defendants"), alleges[1] as follows:

THE PARTIES

1. Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, with a place of business at 100 College Road West, Princeton, New Jersey 08540.

2. Counterclaim-Defendant Astellas Pharma Inc. purports to be a corporation organized and existing under the laws of Japan, having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan. Astellas Pharma Inc. purports to have been formed on April 1, 2005, from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd.

3. Counterclaim-Defendant Astellas Ireland Co., Ltd. ("AICL") purports to be a corporation organized and existing under the laws of Ireland, having its principal place of business at Damastown Road, Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland. AICL purports to be a subsidiary of Plaintiff Astellas Pharma Inc.

4. Counterclaim-Defendant Astellas Pharma Global Development, Inc. ("APGD") purports to be corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062. APGD purports to be a subsidiary of Plaintiff Astellas Pharma Inc.

[1] Sandoz Inc. respectfully provides these amended counterclaims without prejudice to the counterclaims filed on December 19, 2016 (D.I. 12), which were sufficiently pled as filed, in order to avoid unnecessary motion practice.

JURISDICTION AND VENUE

5. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

7. This Court has personal jurisdiction over Counterclaim-Defendants because Counterclaim-Defendants have availed themselves of the rights and privileges—and subjected themselves to the jurisdiction—of this forum by suing Sandoz Inc. in this District, and/or because Counterclaim-Defendants conduct substantial business in, and have regular systemic contact with, this District.

8. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400.

BACKGROUND

A. Myrbetriq® (mirabegron extended-release tablets, 25 mg and 50 mg)

9. APGD purports to be the holder of approved New Drug Application ("NDA") No. 202611 for Myrbetriq® extended-release tablets, 25 mg and 50 mg.

B. Patents-in-Suit

10. On or about March 11, 2008, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 7,342,117 ("the '117 patent").

11. On or about July 19, 2011, the PTO issued U.S. Patent No. 7,982,049 ("the '049 patent").

12. On or about September 16, 2014, the PTO issued U.S. Patent No. 8,835,474 ("the

'474 patent").

13. On or about April 29, 2014, the PTO re-issued U.S. Patent No. RE44,872 ("the '872 patent").

14. Counterclaim-Defendants purport and claim to have the right to enforce the '117, '049, '474, and '872 patents.

15. By listing the '117, '049, '474, and '872 patents in the electronic version of U.S. Food and Drug Administration's ("FDA") publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (a/k/a FDA's Orange Book), Counterclaim-Defendants maintain that an infringement suit could reasonably be asserted against any generic Abbreviated New Drug Application ("ANDA") applicant—including Sandoz Inc.—that attempts to seek approval for, and market, a generic version of Myrbetriq® before patent expiration.

C. Sandoz Inc.'s ANDA for Mirabegron Extended-Release Tablets, 25 mg and 50 mg

16. Sandoz Inc. has filed ANDA No. 209441 with FDA seeking approval for mirabegron extended-release tablets, 25 mg and 50 mg ("Sandoz Inc.'s ANDA").

17. Sandoz Inc.'s ANDA includes certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications") to the '117, '049, '474, and '872 patents, stating that, in Sandoz Inc.'s opinion and to the best of its knowledge, such patents are invalid, unenforceable and/or not infringed.

18. Counterclaim-Defendants sued Sandoz Inc. for alleged infringement of the '117, '049, '474, and '872 patents in this District. Sandoz Inc. denies all allegations of infringement.

COUNT I
Declaratory Judgment of Invalidity of the '117 Patent

19. Sandoz Inc. realleges and incorporates by reference the allegations of paragraphs 1-18 as though fully set forth herein.

20. There is an actual, substantial, and continuing case or controversy between Sandoz Inc. and Counterclaim-Defendants regarding, *inter alia*, the invalidity of the '117 patent.

21. The claims of the '117 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

22. The claims of the '117 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 *et seq.*, including, without limitation, 35 U.S.C. §§ 102 and 103. For example, the claims of the '117 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least International Patent Application Publication No. WO 1998/007445 to Akahane et al., published February 26, 1998 (also published in English as European Patent Application Publication No. EP0958835 on November 24, 1999), alone or in combination with other prior art such as Philip L. Gould, *Salt Selection for Basic Drugs*, 33 INT'L J. PHARMACEUTICS 201 (1986), alone or in combination with other prior art such as J.A. Boatman and J.B. Johnson, *A Four-Stage Approach to New Drug Development*, 5 PHARMACEUTICAL TECH. 46 (1981), alone or in combination with other prior art such as U.S. Patent No. 6,346,532, alone or in combination with other prior art such as J. Keith Guillory, *Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids, in* 95 POLYMORPHISM IN PHARMACEUTICAL SOLIDS 183 (Harry G. Brittain ed., 1999), alone or in combination with other prior art such as Michael J. Jozwiakowski, *Alteration of the Solid State of the Drug Substance: Polymorphs, Solvates, and Amorphous Forms, in* WATER-INSOLUBLE DRUG FORMATION 525 (Rong Liu ed., 2000), alone or in combination with other prior art.

23. Additionally and/or in the alternative, by way of example and not limitation, one or more claims of the ’117 patent are invalid as obvious over claim 6 of the ’532 patent under the doctrine of obviousness-type double patenting, in view of EP 1028111 (“the ’111 publication”) and the general knowledge in the art.

24. One or more claims of the ‘117 patent are invalid under 35 U.S.C. § 112 for (1) failing to comply with the “written description” requirement, (2) failing to comply with the “enablement” requirement, and/or (3) failing to comply with the “definiteness” requirement. For example, the ‘117 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those skilled in the art can conclude that the inventors were in possession of the claimed invention as of the filing date. The ‘117 patent claims also do not satisfy the enablement requirement at least because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. The ‘117 patent claims do not satisfy the definiteness requirement at least because those skilled in the art would not understand the full scope of the ‘117 patent claims when read in the light of the specification.

25. Sandoz reserves the right to provide additional bases for invalidity of the ’117 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

26. Sandoz Inc. is entitled to a judicial declaration that the claims of the ‘117 patent are invalid.

COUNT II
Declaratory Judgment of Non-Infringement of the '117 Patent

27. Sandoz Inc. realleges and incorporates by reference the allegations of paragraphs 1-24 as though fully set forth herein.

28. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Sandoz Inc. and Counterclaim-Defendants concerning the infringement of the '117 patent.

29. Sandoz Inc.'s manufacture, use, offer for sale, sale, importation, and/or marketing of the mirabegron extended-release tablets, 25 mg and 50 mg products described in Sandoz Inc.'s ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '117 patent, either literally or under the doctrine of equivalents, including because each of the claims of the '117 patent that Counterclaim-Defendants could assert against Sandoz Inc. are invalid for failure to comply with 35 U.S.C. §§ 102, 103, and/or 112 and/or double patenting, as set forth above in the First Count of Sandoz Inc.'s counterclaims, and an invalid claim cannot be infringed.

30. Counterclaim-Defendants bear the burden of proving by preponderant evidence that every limitation set forth in the assert claim is found in the accused product, either literally or by a substantial equivalent. To date, Counterclaim-Defendants have not set forth any evidence attempting to prove infringement of the '117 patent.

31. Additionally, by way of example and not limitation, Sandoz's ANDA Product does not contain a crystal of (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-

phenylethyl)amino]ethyl]acetanilide having heat absorption peaks at 90 to 110 °C and at 142 to 146 °C in the DSC analysis and having main peaks at around 9.68, 19.76, 20.72, 22.10 and 23.52 in the terms of 2θ(°) in the powder X-ray diffraction, as recited in claim 2 of the '117 patent. Additionally, for example, Sandoz will not infringe claim 2 of the '117 patent under the doctrine of equivalents because expanding the scope of claim 2 of the '117 patent to encompass Sandoz's ANDA Product would vitiate the specific crystal requirement, and would impermissibly negate at least one claim limitation or element.

32. Sandoz reserves the right to provide additional bases for non-infringement of the '117 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

33. Sandoz Inc. is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the mirabegron extended-release tablets, 25 mg and 50 mg products described in Sandoz Inc.'s ANDA have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '117 patent, either literally or under the doctrine of equivalents.

COUNT III
Declaratory Judgment of Invalidity of the '049 Patent

34. Sandoz Inc. realleges and incorporates by reference the allegations of paragraphs 1-28 as though fully set forth herein.

35. There is an actual, substantial, and continuing case or controversy between Sandoz Inc. and Counterclaim-Defendants regarding, *inter alia*, the invalidity of the '049 patent.

36. The claims of the '049 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

37. The claims of the ‘049 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 *et seq.*, including, without limitation, 35 U.S.C. §§ 102 and 103. For example, the claims of the ‘049 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least International Patent Application Publication No. WO 1998/007445 to Akahane et al., published February 26, 1998 (also published in English as European Patent Application Publication No. EP0958835 on November 24, 1999), alone or in combination with other prior art such as Philip L. Gould, *Salt Selection for Basic Drugs*, 33 INT’L J. PHARMACEUTICS 201 (1986), alone or in combination with other prior art such as J.A. Boatman and J.B. Johnson, *A Four-Stage Approach to New Drug Development*, 5 PHARMACEUTICAL TECH. 46 (1981), alone or in combination with other prior art, alone or in combination with other prior art such as U.S. Patent No. 6,346,532, alone or in combination with other prior art such as J. Keith Guillory, *Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids*, *in* 95 POLYMORPHISM IN PHARMACEUTICAL SOLIDS 183 (Harry G. Brittain ed., 1999), alone or in combination with other prior art such as Michael J. Jozwiakowski, *Alteration of the Solid State of the Drug Substance: Polymorphs, Solvates, and Amorphous Forms*, *in* WATER-INSOLUBLE DRUG FORMATION 525 (Rong Liu ed., 2000) , alone or in combination with other prior art.

38. Additionally or in the alternative, by way of example and not limitation, one or more claims of the ’049 patent are invalid as obvious over claim 12 of the ’532 patent under the doctrine of obviousness-type double patenting, in view of the ’111 publication and the general knowledge in the art.

39. One or more claims of the ‘049 patent are invalid under 35 U.S.C. § 112 for (1) failing to comply with the “written description” requirement, (2) failing to comply with the “enablement” requirement, and/or (3) failing to comply with the “definiteness” requirement. The

‘049 patent claims do not satisfy the written description requirement because the specification fails to describe what is claimed with sufficient detail such that those skilled in the art can conclude that the inventors were in possession of the claimed invention as of the filing date. The ‘049 patent claims also do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the ‘049 patent claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the ‘049 patent claims when read in the light of the specification.

40. Sandoz reserves the right to provide additional bases for invalidity of the ’049 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

41. Sandoz Inc. is entitled to a judicial declaration that the claims of the ‘049 patent are invalid.

COUNT IV
Declaratory Judgment of Non-Infringement of the ‘049 Patent

42. Sandoz Inc. realleges and incorporates by reference the allegations of paragraphs 1-34 as though fully set forth herein.

43. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Sandoz Inc. and Counterclaim-Defendants concerning the infringement of the ‘049 patent.

44. Sandoz Inc.’s manufacture, use, offer for sale, sale, importation, and/or marketing

of the mirabegron extended-release tablets, 25 mg and 50 mg products described in Sandoz Inc.'s ANDA have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '049 patent, either literally or under the doctrine of equivalents, including because each of the claims of the '049 patent that Counterclaim-Defendants could assert against Sandoz Inc. are invalid for failure to comply with 35 U.S.C. §§ 102, 103, and/or 112 and/or double patenting, as set forth above in the Third Count of Sandoz Inc.'s counterclaims, and an invalid claim cannot be infringed.

45. Counterclaim-Defendants bear the burden of proving by preponderant evidence that every limitation set forth in the assert claim is found in the accused product, either literally or by a substantial equivalent. To date, Counterclaim-Defendants have not set forth any evidence attempting to prove infringement of the '049 patent.

46. Additionally, Sandoz will not administer any pharmaceutical composition to patients and therefore will not directly infringe one or more claims of the '049 patent. Additionally, for example, Sandoz's ANDA Product does not contain a β-form crystal of (R)-2-(2-aminothiazol-4-yl)-4-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide as recited in one or more claims of the '049 patent. Furthermore, for example, the use of Sandoz's ANDA Product for treating overactive bladder, in accordance with Sandoz's proposed prescribing information would not infringe one or more claims of the '049 patent, either literally or under the doctrine of equivalents.

47. Sandoz reserves the right to provide additional bases for non-infringement of the '049 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

48. Sandoz Inc. is entitled to a judicial declaration that the manufacture, use, offer for

sale, sale, importation, and/or marketing of the mirabegron extended-release tablets, 25 mg and 50 mg products described in Sandoz Inc.'s ANDA have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '049 patent, either literally or under the doctrine of equivalents.

COUNT V
Declaratory Judgment of Invalidity of the '474 Patent

49. Sandoz Inc. realleges and incorporates by reference the allegations of paragraphs 1-38 as though fully set forth herein.

50. There is an actual, substantial, and continuing case or controversy between Sandoz Inc. and Counterclaim-Defendants regarding, *inter alia*, the invalidity of the '474 patent.

51. The claims of the '474 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

52. The claims of the '474 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 *et seq.*, including, without limitation, 35 U.S.C. §§ 102 and 103. For example, the claims of the '474 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least International Patent Application Publication No. WO 1998/007445 to Akahane et al., published February 26, 1998 (also published in English as European Patent Application Publication No. EP0958835 on November 24, 1999), alone or in combination with other prior art such as Canadian Patent Application Publication No. 2,305,802, alone or in combination with other prior art such as Y. Igawa et al., *Possible β3-Adrenoceptor-Mediated Relaxation of the Human Detrusor*, 164 ACTA PHYSIOLOGICA 117 (1998), alone or in combination with other prior art such as Yasuhiko Igawa et al., *Functional and Molecular Biological Evidence for a Possible β_3-Adrenoceptor in the Human Detrusor Muscle*, 126 BRIT. J. PHARMACOLOGY 819

(1999), alone or in combination with other prior art such as Hiroo Takeda et al., *Effects of* β_3*-Adrenoceptor Stimulation on Prostaglandin* E_2*-Induced Bladder Hyperactivity and on the Cardiovascular System in Conscious Rats*, 21 NEUROUROLOGY & URODYNAMICS 558 (2002), alone or in combination with other prior art such as Masayuki Takeda et al., *Evidence for* β_3*-Adrenoceptor Subtypes in Relaxation of the Human Urinary Bladder Detrusor: Analysis by Molecular Biological and Pharmacological Methods*, 288 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 1367 (1999), alone or in combination with other prior art such as Hiroo Takeda et al., *Role of the* β_3*-Adrenoceptor in Urine Storage in the Rat: Comparison Between the Selective β3-Adrenoceptor Agonist, CL316,243, and Various Smooth Muscle Relaxants*, 293 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 939 (2000), alone or in combination with other prior art such as U.S. Patent No. 6,346,532, alone or in combination with other prior art such as H.M. Dallosso et al., *The Association of Diet and Other Lifestyle Factors with Overactive Bladder and Stress Incontinence: A Longitudinal Study in Women*, 92 BJU INT'L 69 (2003), alone or in combination with other prior art such as Jeanette S. Brown et al., *Urinary Incontinence in Older Women: Who Is at Risk?*, 87 OBSTETRICS & GYNECOLOGY 715 (1996), alone or in combination with other prior art such as S. Mommsen & A. Foldspang, *Body Mass Index and Adult Female Urinary Incontinence*, 12 WORLD J. UROLOGY 319 (1994), alone or in combination with other prior art.

53. Additionally or in the alternative, by way of example and not limitation, one or more claims of the '474 patent are invalid as obvious over at least claims 6 and 13 of the '532 patent under the doctrine of obviousness-type double patenting, in view at least the general knowledge in the art.

54. One or more claims of the '474 patent are invalid under 35 U.S.C. § 112 for (1)

failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and/or (3) failing to comply with the "definiteness" requirement. The '474 patent claims do not satisfy the written description requirement because the specification fails to describe what is claimed with sufficient detail such that those skilled in the art can conclude that the inventors were in possession of the claimed invention as of the filing date. The '474 patent claims also do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the '474 patent claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the '474 patent claims when read in the light of the specification.

55. Sandoz reserves the right to provide additional bases for invalidity of the '474 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

56. Sandoz Inc. is entitled to a judicial declaration that the claims of the '474 patent are invalid.

COUNT VI
Declaratory Judgment of Non-Infringement of the '474 Patent

57. Sandoz Inc. realleges and incorporates by reference the allegations of paragraphs 1-44 as though fully set forth herein.

58. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Sandoz Inc.

and Counterclaim-Defendants concerning the infringement of the ‘474 patent.

59. Counterclaim-Defendants bear the burden of proving by preponderant evidence that every limitation set forth in the assert claim is found in the accused product, either literally or by a substantial equivalent. To date, Counterclaim-Defendants have not set forth any evidence attempting to prove infringement of the ’474 patent.

60. Sandoz Inc.’s manufacture, use, offer for sale, sale, importation, and/or marketing of the mirabegron extended-release tablets, 25 mg and 50 mg products described in Sandoz Inc.’s ANDA have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ‘474 patent, either literally or under the doctrine of equivalents, either literally or under the doctrine of equivalents, including because each of the claims of the ‘474 patent that Counterclaim-Defendants could assert against Sandoz Inc. are invalid for failure to comply with 35 U.S.C. §§ 102, 103, and/or 112 and/or double patenting, as set forth above in the Fifth Count of Sandoz Inc.’s counterclaims, and an invalid claim cannot be infringed.

61. Sandoz reserves the right to provide additional bases for non-infringement of the ’474 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

62. Sandoz Inc. is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the mirabegron extended-release tablets, 25 mg and 50 mg products described in Sandoz Inc.’s ANDA have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ‘474 patent, either literally or under the doctrine of equivalents.

COUNT VII
Declaratory Judgment of Invalidity of the '872 Patent

63. Sandoz Inc. realleges and incorporates by reference the allegations of paragraphs 1-48 as though fully set forth herein.

64. There is an actual, substantial, and continuing case or controversy between Sandoz Inc. and Counterclaim-Defendants regarding, *inter alia*, the invalidity of the '872 patent.

65. The claims of the '872 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

66. The claims of the '872 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 *et seq.*, including, without limitation, 35 U.S.C. §§ 102 and 103. For example, the claims of the '872 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least International Patent Application Publication No. WO 1998/007445 to Akahane et al., published February 26, 1998 (also published in English as European Patent Application Publication No. EP0958835 on November 24, 1999), alone or in combination with other prior art such as Canadian Patent Application Publication No. 2,305,802, alone or in combination with other prior art such as Y. Igawa et al., *Possible β3-Adrenoceptor-Mediated Relaxation of the Human Detrusor*, 164 ACTA PHYSIOLOGICA 117 (1998), alone or in combination with other prior art such as Yasuhiko Igawa et al., *Functional and Molecular Biological Evidence for a Possible β_3-Adrenoceptor in the Human Detrusor Muscle*, 126 BRIT. J. PHARMACOLOGY 819 (1999), alone or in combination with other prior art such as Hiroo Takeda et al., *Effects of β_3-Adrenoceptor Stimulation on Prostaglandin E_2-Induced Bladder Hyperactivity and on the Cardiovascular System in Conscious Rats*, 21 NEUROUROLOGY & URODYNAMICS 558 (2002), alone or in combination with other prior art such as Masayuki Takeda et al., *Evidence for β_3-Adrenoceptor Subtypes in Relaxation of the Human Urinary Bladder Detrusor: Analysis by*

Molecular Biological and Pharmacological Methods, 288 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 1367 (1999), alone or in combination with other prior art such as such as Hiroo Takeda et al., *Role of the β_3-Adrenoceptor in Urine Storage in the Rat: Comparison Between the Selective β_3-Adrenoceptor Agonist, CL316,243, and Various Smooth Muscle Relaxants*, 293 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 939 (2000), alone or in combination with other prior art such as U.S. Patent No. 6,346,532, alone or in combination with other prior art such as H.M. Dallosso et al., *The Association of Diet and Other Lifestyle Factors with Overactive Bladder and Stress Incontinence: A Longitudinal Study in Women*, 92 BJU INT'L 69 (2003), alone or in combination with other prior art such as Jeanette S. Brown et al., *Urinary Incontinence in Older Women: Who Is at Risk?*, 87 OBSTETRICS & GYNECOLOGY 715 (1996) , alone or in combination with other prior art such as S. Mommsen & A. Foldspang, *Body Mass Index and Adult Female Urinary Incontinence*, 12 WORLD J. UROLOGY 319 (1994), alone or in combination with other prior art.

67. Additionally or in the alternative, by way of example and not limitation, one or more claims of the '872 patent are invalid as obvious over at least claims 6 and 13 of the '532 patent under the doctrine of obviousness-type double patenting, in view of at least the general knowledge in the art.

68. One or more claims of the '872 patent are invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and/or (3) failing to comply with the "definiteness" requirement. The '872 patent claims do not satisfy the written description requirement because the specification fails to describe what is claimed with sufficient detail such that those skilled in the art can conclude that the inventors were in possession of the claimed invention as of the filing date. The '872 patent

claims also do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the '872 patent claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the '872 patent claims when read in the light of the specification.

69. Sandoz reserves the right to provide additional bases for invalidity of the '872 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

70. Sandoz Inc. is entitled to a judicial declaration that the claims of the '872 patent are invalid.

COUNT VIII
Declaratory Judgment of Non-Infringement of the '872 Patent

71. Sandoz Inc. realleges and incorporates by reference the allegations of paragraphs 1-54 as though fully set forth herein.

72. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Sandoz Inc. and Counterclaim-Defendants concerning the infringement of the '872 patent.

73. Counterclaim-Defendants bear the burden of proving by preponderant evidence that every limitation set forth in the assert claim is found in the accused product, either literally or by a substantial equivalent. To date, Counterclaim-Defendants have not set forth any evidence attempting to prove infringement of the '872 patent.

74. Sandoz Inc.'s manufacture, use, offer for sale, sale, importation, and/or marketing of the mirabegron extended-release tablets, 25 mg and 50 mg products described in Sandoz Inc.'s ANDA have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '872 patent, either literally or under the doctrine of equivalents, including because each of the claims of the '872 patent that Counterclaim-Defendants could assert against Sandoz Inc. are invalid for failure to comply with 35 U.S.C. §§ 102, 103 and/or 112 and/or double patenting, as set forth above in the Seventh Count of Sandoz's counterclaims, and an invalid claim cannot be infringed.

75. Additionally, for example, the proposed prescribing information for Sandoz's ANDA Product does not indicate administering mirabegron to patients not suffering from diabetes, or wherein the overactive bladder is a result of benign prostatic hyperplasia, as recited in one or more claims of the '872 patent. Nor does the proposed prescribing information for Sandoz's ANDA Product indicate administering mirabegron to patients not suffering from diabetes that have pollakiuria, as recited in one or more claims of the '872 patent. Furthermore, the proposed prescribing information for Sandoz's ANDA Product does not indicate that Sandoz's ANDA Product should be prescribed by doctors for the methods purportedly claimed in the '872 patent.

76. Additionally, for example, Sandoz will not contributorily infringe any claims of the '872 patent because Sandoz's ANDA Product has a substantial non-infringing use, including but not limited to, treatment of overactive bladder in patients suffering from diabetes, and/or patients who do not have benign prostatic hyperplasia or pollakiuria.

77. Sandoz reserves the right to provide additional bases for non-infringement of the '872 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings

filed and/or served later in this action.

78. Sandoz Inc. is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the mirabegron extended-release tablets, 25 mg and 50 mg products described in Sandoz Inc.'s ANDA have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '872 patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Sandoz Inc. respectfully prays for judgment in its favor and against Plaintiffs/Counterclaim-Defendants:

(a) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the mirabegron extended-release tablets, 25 mg and 50 mg products described in Sandoz Inc.'s ANDA have not infringed, do not infringe, and would not—if made used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '117 patent, either literally or under the doctrine of equivalents;

(b) Declaring that the claims of the '117 patent are invalid;

(c) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the mirabegron extended-release tablets, 25 mg and 50 mg products described in Sandoz Inc.'s ANDA have not infringed, do not infringe, and would not—if made used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '049 patent, either literally or under the doctrine of equivalents;

(d) Declaring that the claims of the '049 patent are invalid;

(e) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the mirabegron extended-release tablets, 25 mg and 50 mg products described in Sandoz Inc.'s ANDA have not infringed, do not infringe, and would not—if made used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '474 patent, either literally or under the doctrine of equivalents;

(f) Declaring that the claims of the '474 patent are invalid;

(g) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the mirabegron extended-release tablets, 25 mg and 50 mg products described in Sandoz Inc.'s ANDA have not infringed, do not infringe, and would not—if made used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '872 patent, either literally or under the doctrine of equivalents;

(h) Declaring that the claims of the '872 patent are invalid;

(i) Ordering that Plaintiffs'/Counterclaim-Defendants' Complaint (D.I. 1) be dismissed with prejudice and judgment entered in favor of Sandoz Inc.;

(j) Declaring this case exceptional and awarding Sandoz Inc. its reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and

(k) Awarding Sandoz Inc. such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Sandoz Inc. hereby demands a jury trial on all issues so triable.

HEYMAN ENERIO
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